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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,614	01/09/2002	Ya Fang Liu	YFLU-P03-001	6176

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,614	Applicant(s) LIU, YA FANG	
	Examiner Susan Hanley	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 34 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33, 34 and 44-46 is/are rejected.
- 7) ☒ Claim(s) 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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Susan Hanley is now the examiner for this application. Her contact information can be found at the end of this Office Action.

DETAILED ACTION

Applicant's arguments filed August 4, 2004 are moot in light of new rejections.

Priority

Applicant is being given benefit to the filing date of the parent application 09/156,367 filed on 9/17/98) but is being denied benefit to the provisional application filing date (5/14/98) for 60/085,439. As presently written, the full scope embraced by each claim was not disclosed in the provisional application. The methods as claimed were not disclosed in the provisional application. The provisional application is essentially a research paper and discloses particular experiments performed. There is no generic disclosure of the methods as presently claimed.

Specification

The use of the trademark "Hoechst 3342" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 45 is objected to because of the following informalities: The term "[γ -³²]ATP" is potentially confusing. The brackets in the expression could be mistaken for a deletion by amendment. Further, the

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element designation after the isotope is missing. It is suggested that the term be written as " γ -³²P-ATP" to avoid confusion.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 34 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method for assessing the ability of a compound to prevent neuronal cell death occurring in a mammal comprising administering a compound that specifically inhibits JNK kinase activity, harvesting a neuronal tissue sample from the animal and determining apoptosis in said tissue and comparing the amount of apoptosis in tissue of an animal that has not received the JNK inhibitor. The degree of apoptosis is an indicator of the compounds ability to prevent neuronal cell death in a mammal.

There is no support in the specification for the claimed method. The specification discloses a method for test the potential of a drug to treat a mammal susceptible to a neurological condition by contacting a compound with JNK, measuring the level of JNK kinase activity (p. 14, lines 19-25). There is no mention of administering the compound to a mammal or determining the level of apoptosis in mammalian neuronal cells. A second method is disclosed for determining the effect of JNK inhibitors on the physiological status of an animal comprising administering a JNK inhibitor to an animal, sacrificing the animal and examining the tissue for apoptosis (p. 17, lines 16-26). This assay appears to be related to determining the safety of JNK inhibitor in a mammal. The disclosure for this method does not link the

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amount of apoptosis in a tissue with the ability of the compound to prevent neuronal cell death. Thus, claim 33 appears to be an melding of the cited disclosure. However, the specification does not disclose an link between the two methods to support the instant claims.

Claims 33, 34 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for determining the ability of a compound to prevent neuronal cell death in a mammal comprising administering a JNK inhibitor to a mammal and determining the degree of apoptosis in neuronal tissue. The limited showing of a reduction in apoptosis in cell culture after contacting the cell culture with a JNK inhibitor is not sufficient to enable a claim drawn to a method for the determination of a JNK inhibitor's ability to prevent neuronal cell death in a mammal since because the arts of biochemistry and medicine are too unpredictable.

The specification does not disclose if one skilled in the art can utilize the claimed assay to determine the prevention of neuronal apoptosis in a mammal with a reasonable expectation of results. Prevention means to keep from occurring. It would be difficult to obtain data to show that a JNK inhibitor is keeping the neurons of a mammal safe from apoptosis 100% of the time. Further, the specification does not demonstrate a link that shows that in vitro inhibition of JNK kinase will prevent apoptosis in neuronal mammalian cells. Thus, the limited disclosure cannot be extrapolated by the ordinary artisan to predict how said assay will predict with absolute certainty that a JNK inhibitor will prevent mammalian neuronal apoptosis.

Claims drawn to pharmaceutically acceptable compositions and to methods of administering said compositions to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The specification supports the use of JNK inhibitor to

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reduce the incidence of apoptosis in cell culture. However, there is no clear connection between the results for the *in vitro* and *in vivo* administration of a JNK inhibitor that would enable a person of ordinary skill in the art to obtain similar results. Hence, the ordinary artisan would be unable to predict an effective therapy using a JNK inhibitor for the prevention of mammalian neuronal cell death that is supported by the specification and expect to obtain similar clinical results. If the administration of a JNK inhibitor to prevent neuronal cell death in a cell culture is not generally applicable for preventing mammalian neuronal cell death, then the treatment of mammals susceptible to a neurological condition with JNK inhibitors would have to be considered individually. This would be considered undue experimentation. Thus, claims 33, 34 and 44-46 are not commensurate in scope with the enabling disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected because the phrase "a change in apoptosis in the neuronal tissue sample" is vague and indefinite. The metes and bounds of the type or characteristics of the "change" are undefined. Appropriate correction is required.

Claim 46 is rejected because it cites the trademark, "Hoechst 3342" which is vague and indefinite. The relationship between a trademark and the product it identifies is sometimes indefinite, uncertain and arbitrary. The formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark. In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant. Arbitrary trademarks which are liable to mean different things at the pleasure of manufacturers do not constitute such language. Ex Parte Kattwinkle, 12 USPQ 11 (Bd. App. 1931).

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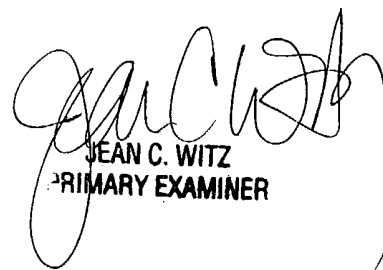
Claim 33 is rejected because it lacks a step that relates the JNK inhibitory properties of the test compound with in vivo apoptosis and prevention of neuronal cell death.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


JEAN C. WITZ
PRIMARY EXAMINER